

AMENDMENT OF THE CLAIMS

1-25. (Withdrawn)

26. (New) A process for producing a pharmaceutical composition comprising the steps:

- (a) forming a feed solution comprising a drug, a concentration-enhancing polymer and a solvent;
- (b) directing said feed solution to a spray-drying apparatus comprising
 - (i) a drying chamber having a volume V_{dryer} and a height H ,
 - (ii) atomizing means for atomizing said feed solution into droplets, and
 - (iii) a source of heated drying gas for drying said droplets, said source delivering said drying gas to said drying chamber at a flow rate of G ,

wherein V_{dryer} is measured in m^3 ,

H is at least 1 m,

G is measured in m^3/sec ,

and wherein the following mathematical relationship is satisfied

$$\frac{V_{\text{dryer}}}{G} \geq 10 \text{ seconds};$$

- (c) atomizing said feed solution into droplets in said drying chamber by said atomizing means, said droplets having an average diameter of at least $50 \mu\text{m}$ and a D_{10} of at least $10 \mu\text{m}$;
- (d) contacting said droplets with said heated drying gas to form particulates of a solid amorphous dispersion of said drug and said concentration-enhancing polymer; and
- (e) collecting said particulates.

27. (New) The process of claim 26 wherein said droplets have a D_{10} of at least $15 \mu\text{m}$.

28. (New) The process of claim 27 wherein said droplets have a D_{10} of at least $20 \mu\text{m}$.

29. (New) The process of claim 26 wherein said droplets have a Span of less than about 3.

30. (New) The process of claim 26 wherein said droplets have a Span of less than about 2.

31. (New) The process of claim 26 wherein at least 80 vol% of said particulates have diameters of greater than 10 μm .

32. (New) The process of claim 31 wherein at least 90 vol% of said particulates have diameters of greater than 10 μm .

33. (New) The process of claim 26 wherein said drug in said dispersion is substantially amorphous and said dispersion is substantially homogeneous.

34. (New) The process of claim 26 wherein said drug is selected from the group consisting of antihypertensives, antianxiety agents, anticlotting agents, anticonvulsants, blood glucose-lowering agents, decongestants, antihistamines, antitussives, antineoplastics, beta blockers, anti-inflammatories, antipsychotic agents, cognitive enhancers, anti-atherosclerotic agents, cholesterol-reducing agents, antiobesity agents, autoimmune disorder agents, anti-impotence agents, antibacterial and antifungal agents, hypnotic agents, anti-Parkinsonism agents, anti-Alzheimer's disease agents, antibiotics, anti-depressants, antiviral agents, glycogen phosphorylase inhibitors, and cholesteryl ester transfer protein inhibitors.

35. (New) The process of claim 26 wherein said drug is selected from the group consisting of [2R,4S] 4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester; [2R,4S]-4-[acetyl-(3,5-bis-trifluoromethyl-benzyl)-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid isopropyl ester; and [2R,4S] 4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid isopropyl ester.

36. (New) The process of claim 26 wherein said concentration-enhancing polymer is selected from the group consisting of ionizable cellulosic polymers, non-ionizable

cellulosic polymers, ionizable non-cellulosic polymers, non-ionizable non-cellulosic polymers, neutralized acidic polymers and blends thereof.

37. (New) The process of claim 26 wherein said polymer is selected from the group consisting of hydroxypropyl methyl cellulose, hydroxypropyl cellulose, carboxymethyl ethyl cellulose, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl alcohols that have at least a portion of their repeat units in hydrolyzed form, polyvinyl pyrrolidone, poloxamers, and blends thereof.

38. (New) The process of claim 26 wherein said polymer is hydroxypropyl methyl cellulose acetate succinate.

39. (New) The process of claim 26 wherein said drug is [2R,4S] 4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester and said polymer is hydroxypropyl methyl cellulose acetate succinate.

40. (New) The process of claim 26 wherein said particles have an average diameter of at least 40 μm .

41. (New) The process of claim 26 wherein said particles have an average diameter of at least 50 μm .

42. (New) The process of claim 26 wherein said particles have a bulk specific volume of less than 5 mL/g.

43. (New) The process of claim 26 wherein said particles have a bulk specific volume of less than 4 mL/g.

44. (New) The process of claim 26 wherein said concentration-enhancing polymer is present in an amount sufficient such that said solid amorphous dispersion, following administration to an *in vivo* or *in vitro* use environment, provides concentration enhancement of said drug in said use environment relative to a control composition consisting essentially of an equivalent amount of said drug alone.

45. (New) The process of claim 44 wherein said composition provides a maximum drug concentration of said drug in said use environment that is at least about 1.25-fold that provided by said control composition.
46. (New) The process of claim 44 wherein said composition provides in said use environment an area under the drug concentration versus time curve for any 90-minute period from the time of introduction to about 270 minutes following introduction to said use environment that is at least 1.25-fold that provided by said control composition.
47. (New) The process of claim 44 wherein said composition provides a relative bioavailability of said drug that is at least 1.25-fold that of said control composition.
48. (New) The process of claim 26 wherein said spray-drying apparatus further comprises a gas disperser for dispersing said gas into said drying chamber.
49. (New) The process of claim 48 wherein said drying gas is dispersed into said drying chamber such that the primary axis of flow of said drying gas is parallel to the axis of said atomizing means.
50. (New) The product of the process of any of claims 26-49.